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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,250	02/28/2002	Paul D. Rubin	4821-469	4257

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,250	RUBIN, PAUL D.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16,30-41 and 50-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16,30-41 and 50-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendments and response filed 05/27/04 is acknowledged. Claims 12-16, 30-41, 50-66 are pending and subject to examination.

A showing by the applicant that the supportive prior art, Woosley et al, was commonly owned by Sepracore Inc. at the time this application was filed, necessitated a new search and consideration of the claims. Thus the new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16, 30-41, 50-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating allergic rhinitis, does not reasonably provide enablement for preventing allergic rhinitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are

weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides a method of treating allergic rhinitis in a human comprising administering to a human a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof, and a therapeutically effective amount of a leukotriene inhibitor, or a pharmaceutically acceptable salt thereof.

(2) The state of the prior art

The prior art teaches methods of treating allergic disorders by administering a composition comprising a combination of active agents including leukotriene receptor antagonist, antihistamines, etc.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of preventing an allergic condition or disease in the art is very high. Prevention of any disorder, especially allergic disorders is unpredictable because, for example, the origin or cause of allergic conditions vary. There are numerous underlying factors known to cause or affect individuals diagnosed with allergic conditions such as allergic rhinitis. While treating most allergic conditions have been researched extensively over the years, and have shown success with certain methods of treatments, prevention of allergic conditions has not yet been successful.

(5) The breadth of the claims

The claims are relatively broad. The scope of the claimed "method of treating or PREVENTING allergic rhinitis in a human" appears too broad to be discussed in any one disclosure.

(6) The amount of direction or guidance presented

The specification does not provide adequate direction to one or ordinary skill how to prevent allergic rhinitis in a human using the claimed composition. The specification provides no guidance, in the way of written description, as to how to make and use the invention to its fullest claimed scope. The specification does not provide any written description in the form of disclosed method of prevention of allergic rhinitis. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the methods will fall within the scope of a claim and will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

As stated above, the specification provides no working examples for prevention of allergic rhinitis.

(8) The quantity of experimentation necessary
Since there are no known methods of prevention in the art, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the applicability or effectiveness of the claimed method of prevention.

In view of the unpredictability in the art, the lack of working examples, and lack of guidance in the specification, it would require undue experimentation on the part of the person of skill in the art to practice the full scope of the invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-16, 30-41, 50-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoh (5,120,758) in view of Aslanian (5,990,147).

Satoh teaches pharmaceutical formulations comprising an effective amount of a lipoxygenase inhibitor either alone or in combination with another therapeutic agent selected from anti-inflammatory, antihistamines, etc (col. 13, lines 13-21). Examples of antihistaminic agents include astemizole (col. 13, lines 36-37). Satoh also discloses that the invention relates to a method of inhibiting 5-lipoxygenase activity in mammals including man, and of treating diseases and conditions responsive thereto, particularly inflammatory and allergic disorders, such as allergic rhinitis (col. 13, lines 49-63). Satoh while disclosing class of antihistamines, lacks specific disclosure on norastemizole.

Aslanian teaches formulations comprising a combination of a phenyl-alkyl-imidazole with an H3 receptor and a method for treatment of upper airway allergic responses comprising administering a compound, or salt or solvate thereof of formula I in combination with a histamine H1 receptor antagonist (col. 3, lines 31-58).

Aslanina teaches that examples of suitable histamine receptor agents include astemizole, norastemizole, etc (col. 4, lines 41-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Satoh on formulations comprising a leukotriene and a second active agent such as an antihistamine, including astemizole to have looked in the art for other specific antihistamines, as disclosed by Aslanian, with the reasonable expectations of successfully preparing formulations that effectively treats allergic conditions such as allergic rhinitis.

Furthermore, It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two known anti-allergic agents. It would follow that the recited claims define prima facie obvious subject matter.

Response to Arguments

Applicant's arguments, filed 05/27/04, with respect to the rejection of claim(s) under Satoh in view of Woosley et al have been fully considered and are partly persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Satoh and Aslanian.

Since Satoh is maintained as the primary reference, Applicant's arguments regarding the said prior art will be addressed here.

Applicant argues that Satoh discloses a genus of compounds that can be used as 5-lipoxygenase inhibitors and other active agents. Applicant believes that "Satoh does not place any limits as to what another therapeutic agent may be". Applicant also states that "There is no teaching or suggestion whatsoever in Satoh as to whether any specific antihistaminic agent would be particularly desirable when in combination with 5-lipoxygenase inhibitors to which it is directed". However the arguments are not commensurate with the scope of the claims. 1) Instant claims require a leukotriene inhibitor such as a 5-lipoxygenase inhibitor or a leukotriene receptor antagonist. Satoh also discloses lipoxygenase inhibitors such as leukotriene receptor antagonist. 2) Satoh discloses combination of agents for treating allergic conditions such as rhinitis. The combinations are clearly stated as a lipoxygenase inhibitor with a second active agent such as antihistamines. It would be obvious to one of ordinary skill to combine an anti-allergic medication to a composition that is taught useful for treating allergies. There does not appear to be a need for undue experimentation. It is noted that Satoh was and

is used in a 103, obviousness rejection and certain amount of picking and choosing amongst the disclosed species is permitted.

It is further noted that the instant specification does not disclose any unexpected result form combining norastemizole with a leukotriene inhibitor. Absent any unexpected results and the criticality of the said specific combination, it is considered that any of the antihistamine agents disclosed by Satoh combined with the leukotriene receptor antagonist would be desirable for treating allergic rhinitis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
August 31, 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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